35 U.S.C. § 112 because of claims by the examiner that the specification did not enable for **any indicator and any analyte**. The applicant agrees.

The specification was very specific concerning the indicators, buffers, and analytes as taught to exacting detail in the multiple example illustrated in the specification which were very specific for this invention. Therefore, the addition of new claims 8 – 12 using the Examiners helpful suggestions to overcome the § 112 rejections are enclosed.

The Claims Rejection Under 35 USC § 102

The newly deleted and added claims have overcome the Examiners rejection of claims 1-4, 6 and 7 under 35 U.S.C. 102(b) as being anticipated by Gold. This reference describes a method for the identification of nucleic acid ligands. As specifically taught in this specification this technology is not for the identification of nucleic acid ligands. The antiquated technology of Gold is many years old and was never implemented because it does not work and has nothing to do with the present art of a method for the diagnostics determination of analytes of interest using nucleounits. The Gold has no similar reference even remotely resembling the present art. The attempt to use an ancient prior art that lacks implementation is a strained interpretation of the present art and has no relative bearing. The applicant would urge the examiner to use any of the examples as taught in the present specification and find the same example in any of Golds specification. The current device does not use nucleic acid ligands and its limitation is used in the new claims. The present art does not use nucleic acid ligands and demonstrates distinct physical features that clears any § 102 rejections with reference to Gold. Gold device requires the use of candidate mixtures, affinity nucleic acids, nucleic acid binding protein, etc. It goes on and on. The Smith patent has no such **limitations**. The physical features of Smith are completely different (**novel**) from that of Gold clearing the claims of Smith from any §102 rejections. This is patentably distinct and "novel" in structure

and functionality over the Gold device. Because of this and other reasons the Smith device is not limited to all of the requirements of the Gold device.

Rejection to newly added claims 8-15 as being anticipated by Gold under 35 U.S.C. § 102 should be reversed because Gold does not teach applicant's limitations as claimed, i.e., the non-requirement of nucleic acid ligands as required by Gold. Therefore, Gold fails the first step of inquiry with respect to a **35 U.S.C. § 102** rejection anticipation reference. See *In re Spada*, 15 USPQ 2d 1655, 1656 (CAFC 1990) where the Court of Appeals For the Federal circuit stated, "Rejection for anticipation or lack of novelty requires, as the first step in the inquiry, that all elements of the elements of the claimed invention be described in a single reference." In addition, the Court stated, "Further, the reference must describe the applicant's claimed invention sufficiently to have placed a person of ordinary skill in the field of the invention in possession of it." This Gold reference does not because it fails to disclose the use of a dry chemistry or liquid chemistry methods for the determination of analytes of interest without the use of nucleic acid ligands.

The device of Smith uses a "**new principle of operation**" in that the use of nucleounits in a buffer solution are very specific for analytes of interest. Never taught by Gold or any other prior art. The applicants invention solves a different problem than the reference, and such differences are cited in the amended claims, such as no requirement for nucleic acid ligands. See *In re Wright*, 6 USPQ 2d 1959 (1988). Since the Examiner's argument does not support a rejection of the newly amended claims under 35 U.S.C. 102, and because the invention of Smith recites numerous novel physical features that would clear any § 102 rejections the decision to reject the claims based on 35 U.S.C. § 102 should be reversed.

The newly deleted and added claims have overcome the Examiners rejection of claims 1-4, 6 and 7 under 35 U.S.C. 102(b) as being anticipated by Heilig. This reference describes a method for the complexing of nucleic acid ligands to tissue targets. The Smith

art has no such limitation and would not want to use anything even remotely similar this the prior art s antiquated and ancient reference. As specifically taught in this specification this technology is not for the attachment of nucleic acid ligands to target tissue. The antiquated technology of Heilig is many years old (why a patent was awarded for this art is anyone guess) and was and will never implemented because it does not work and has nothing to do with the present art of a method for the diagnostics determination of analytes of interest using nucleounits. The Heilig method has no similar reference even remotely resembling the present art. The attempt to use an ancient prior art that lacks implementation is a strained interpretation of the present art and has no relative bearing. The applicant would urge the examiner to use any of the examples as taught in the present specification and find the same example in any of Heilig specification. The current device does not use tissue targeted nucleic acid ligands and its limitation is used in the new claims. The present art does not use tissue targeted nucleic acid ligands and demonstrates distinct physical features that clears any § 102 rejections with reference to Heilig. The Heilig device requires the use of tissue targets, nucleic acid ligands, a pharmeceutical to the brain, transporter molecule (to get across the blood brain barrier?), transporter molecule-ligand-pharmaceutical conjugate complex(?). The Smith patent has no such **limitations**. The physical features of Smith are completely different (**novel**) from that of Heilig clearing the claims of Smith from any §102 rejections. This is patentably distinct and "novel" in structure and functionality over the Heilig device. Because of this and other reasons the Smith device is not limited to all of the requirements of the Heilig device. Talk about dysfunctional patent(s) that have no relative bearing this art is way out in left field to anything much less the Smith invention.

Rejection to newly added claims 8-15 as being anticipated by Heilig under 35 U.S.C. § 102 should be reversed because Heilig does not teach applicant's limitations as claimed, i.e., the non-requirement of nucleic acid ligands, brain tissue, molecule-ligand-pharmaceutical conjugate complex, as required by Heilig. Therefore, Heilig fails the first

step of inquiry with respect to a **35 U.S.C. § 102** rejection anticipation reference. See *In re Spada*, 15 USPQ 2d 1655, 1656 (CAFC 1990) where the Court of Appeals For the Federal circuit stated, "Rejection for anticipation or lack of novelty requires, as the first step in the inquiry, that all elements of the elements of the claimed invention be described in a single reference." In addition, the Court stated, "Further, the reference must describe the applicant's claimed invention sufficiently to have placed a person of ordinary skill in the field of the invention in possession of it." This Heilig reference does not because it fails to disclose the use of a dry chemistry or liquid chemistry methods for the determination of analytes of interest without the use of nucleic acid ligands or brain tissue, etc.

The device of Smith uses a "**new principle of operation**" in that the use of nucleounits in a buffer solution are very specific for analytes of interest. Never taught by Heilig or any other prior art. The applicants invention solves a different problem than the reference, and such differences are cited in the amended claims, such as no requirement for nucleic acid ligands, brain tissue, and molecule-ligand-pharmaceutical conjugate complexes. See *In re Wright*, 6 USPQ 2d 1959 (1988). Since the Examiner's argument does not support a rejection of the newly amended claims under 35 U.S.C. 102, and because the invention of Smith recites numerous novel physical features that would clear any § 102 rejections the decision to reject the claims based on 35 U.S.C. § 102 should be reversed.

The newly deleted and added claims have overcome the Examiners rejection of claims 1-4, 6 and 7 under 35 U.S.C. 102(b) as being anticipated by Cubicciotti. This reference describes a method for multimolecular devices, drug delivery systems using heteropolymers which requires the use of scanning probe microscopy, optical trapping or flow cytometry. The Smith art has no such limitations and would not want to use anything even remotely similar this prior arts reference. As specifically taught in this specification this technology is not for the attachment of nucleic acid ligands to target

tissue or drug delivery systems using heteropolymers which requires the use of scanning probe microscopy, optical trapping or flow cytometry. What has this to do with the price of tea in China? This bizarre technology of Cubicciotti is non-functional and has not been used commercially as far as the applicant can find out (again, why a patent was awarded for this art is anyone guess) and was and will never implemented because it does not work and has nothing to do with the present art of a method for the diagnostics determination of analytes of interest using nucleounits. The Cubicciotti method has no similar reference even remotely resembling the present art. The attempt to use this prior art that lacks implementation is a strained interpretation of the present art and has no relative bearing. The applicant would urge the examiner to use any of the examples as taught in the present specification and find the same example in any of Cubicciotti specification. The current device does not use tissue targeted nucleic acid ligands or drug delivery systems using heteropolymers which requires the use of scanning probe microscopy, optical trapping or flow cytometry and its limitation is used in the new claims. The present art does not use tissue targeted nucleic acid ligands or drug delivery systems using heteropolymers which requires the use of scanning probe microscopy, optical trapping or flow cytometry and demonstrates distinct physical features that clears any § 102 rejections with reference to Cubicciotti. The Cubicciotti device requires the use of drug delivery systems using heteropolymers which requires the use of scanning probe microscopy, optical trapping or flow cytometry. The Smith patent has no such **limitations**. The physical features of Smith are completely different (**novel**) from that of Cubicciotti clearing the claims of Smith from any §102 rejections. This is patentably distinct and "novel" in structure and functionality over the Cubicciotti device. Because of this and other reasons the Smith device is not limited to all of the requirements of the Cubicciotti device.

Rejection to newly added claims 8-15 as being anticipated by Cubiccinoti under 35 U.S.C. § 102 should be reversed because Cubiccinoti does not teach applicant's

limitations as claimed, i.e., drug delivery systems using heteropolymers which requires the use of scanning probe microscopy, optical trapping or flow cytometry, as required by Cubicciotti. Therefore, Cubicciotti fails the first step of inquiry with respect to a **35 U.S.C. § 102** rejection anticipation reference. See *In re Spada*, 15 USPQ 2d 1655, 1656 (CAFC 1990) where the Court of Appeals For the Federal circuit stated, "Rejection for anticipation or lack of novelty requires, as the first step in the inquiry, that all elements of the elements of the claimed invention be described in a single reference." In addition, the Court stated, "Further, the reference must describe the applicant's claimed invention sufficiently to have placed a person of ordinary skill in the field of the invention in possession of it." This Cubicciotti reference does not because it fails to disclose the use of a dry chemistry or liquid chemistry methods for the determination of analytes of interest without the use of drug delivery systems using heteropolymers which requires the use of scanning probe microscopy, optical trapping or flow cytometry.

The device of Smith uses a "**new principle of operation**" in that the use of nucleounits in a buffer solution are very specific for analytes of interest. Never taught by Cubicciotti or any other prior art. The applicants invention solves a different problem than the reference, and such differences are cited in the amended claims, such as no requirement for nucleic acid ligands or drug delivery systems using heteropolymers which requires the use of scanning probe microscopy, optical trapping or flow cytometry. See *In re Wright*, 6 USPQ 2d 1959 (1988). Since the Examiner's argument does not support a rejection of the newly amended claims under 35 U.S.C. 102, and because the invention of Smith recites numerous novel physical features that would clear any § 102 rejections the decision to reject the claims based on 35 U.S.C. § 102 should be reversed.

Claims 1-4, 6 and 7 were rejected under 35 U.S.C. § 102 as being anticipated by Heilig, Gold and Cubicciotti. The obvious needs to be stated these prior arts do not mention anywhere the methods as described by the present art and cannot be remotely related.

Any rejection of newly added claims 8-15 under 35 U.S.C. § 102 as being anticipated by the prior art should be rejected and is unpatentably not possible. Because applicant's newly added claims 8 - 15 recite novel physical features (i.e., it clears § 102). The novel physical distinctions of claims 8–15 are unobvious under § 102 for the following reasons. The present device produces **unexpected results** due to the inherent design and capability differences between the Smith and the cited prior art. The prior art does not mention the any of the method of Smith in any detail.. When the present and past devices are juxtapose the results produced are unexpected. The present device is a method for the detection of analytes of interest using nucleounits in urine or other fluids effectively allowing **superior** results with reference to time, cost, and accuracy and ability to do the basic claim as made. The present device **omits** certain and critical **elements** of the prior art. The present art by not including these elements of the prior art is in fact more capable of producing a **clinically significant** result for the presence of analytes of interest urine or other fluids therefore producing a **superior** functional device. The prior art does not explain any of the present arts novel features. The prior art fail to teach or mention in any of their specifications or claims the important step of the detection of analytes of interest using nucleounits. The Examiner has not presented a convincing line of reasoning as to why the claimed subject matter as a whole, including its differences over the prior art, would have been obvious. None of the present art teaches the present art. The applicant's invention **solves a different problem.**

As the Appellant and other courts have cited, hindsight view of prior art is not allowable. As the Courts have stated, "It is impermissible to use the claimed invention as an instruction manual to "template" or piece together the teachings of the prior art so that the claimed invention is rendered obvious. This court has previously stated that one cannot use hindsight construction to pick and choose among isolated disclosures in the prior art to depreciate the claimed invention." in re Fritch supra, 1784.

Thus the applicant submits that the present invention clearly recites novel physical subject matter which distinguishes over any possible use of Gold, Heilig or Cubicciotti.

The Novel Physical features of Claims 8 –15 Produce New And Unexpected Results And Hence Are Unobvious And Patentable Over The Reference Under § 102.

Again, Such hindsight reconstruction of an invention to support a rejection under 35 U.S.C. 103 is improper as clearly set forth by the Court of Appeals For the Federal Circuit in *In re Fritch*, 23 USPQ 2d 1780 at 1783-1784 (CAFC 1992) where it is stated, "Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination" ..... "Here, the Examiner relied upon hindsight to arrive at the determination of obviousness. It is impermissible to use the claimed invention as an instruction manual or `template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious. This Court has previously stated that `[o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures of the prior art to deprecate the claimed invention'."

In line with these decisions, recently the Board stated in Ex parte Levengood, 28 U.S.P.Q.2d 1300 (P.T.O.B.A.&I. 1993):

"In order to establish a ***prima facie*** case of the obviousness, it is necessary for the examiner to present ***evidence***, preferable in the form of some teaching, suggestion, incentive or inference in the applied prior art, or in the form of generally available knowledge, that one having ordinary skill in the art ***would have been led*** to combine the relevant teachings of the applied references in the proposed manner to arrive at the claimed invention. ...That which is within the capabilities of one skilled in the art is not synonymous with obviousness. ... That one can ***reconstruct*** and/or explain the theoretical mechanism of an invention by mean of logic and sound scientific reasoning does not afford the basis for an obviousness conclusion unless that logic and reasoning also

supplies sufficient impetus to have led one of ordinary skill in the art to combine the teachings of the references to make the claimed invention.... Our reviewing courts have often advised the Patent and Trademark Office that it can satisfy the burden of establishing a ***prima facie*** case of obviousness only by showing some objective teaching in either prior art, or knowledge generally available to one of ordinary skill in the art, that 'would lead' that individual 'to combine the relevant teachings of the references.' ... Accordingly, an examiner cannot establish obviousness by locating references which describe various aspects of a patent applicant's invention without also providing evidence of the ***motivating force*** which would impel one skilled in the art to do what the ***applicant has done."***

The Novel Physical Features Of Amended Claims 8-15 Produce New And Unexpected Results And Hence Are Unobvious And Patentable Over The References Under § 103.

Conclusion

For all of the above reasons, applicant submits that the specification and claims are now in proper form, and that the claims all define patentably over the prior art. Therefore the applicant submits that this application is now in condition for allowance, which action is respectfully solicited.

Conditional Request For Constructive Assistance

Applicants have amended the specification and claims of this application so that they are proper, definite, and define novel structure which is also unobvious. If, for any reason this application is not believed to be in full condition for allowance, applicant respectfully requests the constructive assistance and suggestions of the Examiner pursuant to M.P.E.P. § 107.03(d) and § 707.07(j) in order that the undersigned can place this

application in allowable condition as soon as possible and without the need for further proceedings.

Very Respectfully Submitted,

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signed Jack V. Smith

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